

REMARKS

Claims 34-37, 57-69, 74-77, 101, and 102 are pending and stand rejected. Claims 34, 57-62, 64-69, 74-76, 101, and 102 have been amended. Claims 103-118 have been added. Reconsideration and allowance of Claims 34-37, 57-69, 74-77, 101, and 102-118 in view of the above amendments and following remarks is respectfully requested.

The Rejection of Claims 57-62, 64-67, 74-77, 101, and 102

Under 35 U.S.C. § 112, Second Paragraph

Claims 57-62, 64-67, 74-77, 101, and 102 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite for reciting the transition "comprising" in a claim that depends from an independent claim that recites the transition "consisting essentially of". Dependent Claims 57-62 and 64-67 have been amended to delete the transition "comprising". Independent Claims 74, 101, and 102 have also been amended to delete the transition "comprising". In view of these amendments, withdrawal of the rejection is respectfully requested.

The Obviousness-Type Double Patenting Rejection

Claims 34-37, 57-69, 74-77, 101, and 102 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-36 of U.S. Patent No. 6,165,509. Withdrawal of this grounds for rejection is respectfully requested for the following reasons.

Claim 1, the only independent claim of the '509 patent, recites a PEGylated drug complexed with a bioadhesive polymer, wherein the PEGylated drug comprises a polyethylene glycol covalently bonded to the drug, and wherein the bioadhesive polymer is selected from polyacrylic acid, polymethacrylic acid, polyethylacrylic acid, and chitosan, or is a random block or graft copolymer comprising polyacrylic acid, polymethacrylic acid, or polyethylacrylic acid. The drug component of the complex dissociates from the bioadhesive polymer under certain

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pH conditions. See Col. 5, lines 9-29. The complex is "particularly useful for the sustained and/or controlled release of a drug". See Col. 5, lines 50-53.

Independent Claims 34, 74, 101, and 102.

Independent Claims 34, 74, 101, and 102 have been amended to recite that the therapeutic or diagnostic agent is covalently coupled to the transport agent. The '509 patent fails to teach or suggest a complex that includes a transport agent (i.e., polymer) covalently coupled to a therapeutic or diagnostic agent, as now claimed. The '509 patent describes and claims a complex that is pH sensitive and from which a PEGylated drug dissociates. In the presently claimed invention, the therapeutic or diagnostic agent is covalently coupled to the transport agent and cannot dissociate from the transport agent. Because the cited patent fails to teach or suggest the invention as now claimed, the claimed invention is nonobvious in view of the teaching of the patent. The invention as now claimed is also nonobvious in view of the patent's claims. Withdrawal of the obviousness-type double patenting rejection is respectfully requested.

New Claims 103-106

Independent Claims 103-106 have been added. Claims 103-106 correspond to independent Claims 34, 74, 101, and 102. However, rather than relating to polycarboxylic acid polymers selected from the group consisting of poly(ethylacrylic acid), poly(propylacrylic acid), poly(butylacrylic acid), and mixtures thereof (as recited in Claims 34, 74, 101, and 102), Claims 103-106 relate to polycarboxylic acid polymers selected from the group consisting of poly(propylacrylic acid), poly(butylacrylic acid), and mixtures thereof. Poly(ethylacrylic acid), which is cited in the U.S. Patent No. 6,165,509 as a bioadhesive polymer and component of the described complex, is not a polycarboxylic acid polymer recited in the invention as now claimed. Because the '509 patent fails to teach, suggest, or provide any motivation to use polycarboxylic acid polymers selected from the group consisting of poly(propylacrylic acid), poly(butylacrylic

acid), and mixtures thereof, as in the claimed invention, the invention as now claimed is nonobvious and patentable over the cited reference.

New Claims 107-118: Copolymer Transport Agents

Graft and Block Copolymers. Claims 107-118 have been added. Claims 107 and 108 are independent claims that correspond to independent Claims 103 and 104. However, rather than relating to polycarboxylic acid polymers selected from the group consisting of poly(propylacrylic acid), poly(butylacrylic acid), and mixtures thereof (as recited in Claims 103 and 104), Claims 107 and 108 relate to transport agents that are graft or block copolymers that include acrylic acid groups or alkyl substituted acrylic acid groups, with the proviso that the copolymers include either propylacrylic acid groups or butylacrylic acid groups. Support for the new claims can be found in the specification as originally filed, for example, at page 10, line 31 through page 11, line 8. Because the '509 patent fails to teach, suggest, or provide any motivation to use the recited graft or block copolymers that include either propylacrylic acid groups or butylacrylic acid groups, the invention of Claims 107 and 108 is nonobvious and patentable over the '509 reference.

Claims 109-112 are dependent claims. Claims 109 and 110 depend from Claim 107 and Claims 111 and 112 depend from Claim 108. Claims 109 and 111 recite that the copolymer includes ethyl acrylate groups, propyl acrylate groups, or butyl acrylate groups. Support for Claims 109 and 111 can be found in the specification as originally filed, for example, at page 10, line 31 through page 11, line 8; at page 12, lines 21-32; and in Example 1, pages 29-32. Claims 110 and 112 recite that alkyl substituted acrylic acid groups include methacrylic acid groups, ethylacrylic acid groups, propylacrylic acid groups, and butylacrylic acid groups. Support for Claims 110 and 112 can be found in the specification as originally filed, for example, at page 10, line 31 through page 11, line 8.

Random Copolymers. Claims 113 and 114 are independent claims that relate to transport agents that are random copolymers that include acrylic acid groups or alkyl substituted acrylic acid groups. Support for the new claims can be found in the specification as originally filed, for example, at page 10, line 31 through page 11, line 8. The '509 patent describes a random block copolymer comprising polyacrylic acid, polymethacrylic acid, or polyethylacrylic acid. The '509 patent does not describe a random copolymer. Because the recited copolymer is a random copolymer and not a random block copolymer, the '509 patent fails to teach, suggest, or provide any motivation to use the recited random copolymer, the invention of Claims 113 and 114 is nonobvious and patentable over the '509 reference.

Claims 115-118 are dependent claims. Claims 115 and 116 depend from Claim 113 and Claims 117 and 118 depend from Claim 114. Claims 115 and 117 recite that the copolymer includes ethyl acrylate groups, propyl acrylate groups, or butyl acrylate groups. Support for Claims 115 and 117 can be found in the specification as originally filed, for example, at page 10, line 31 through page 11, line 8; at page 12, lines 21-32; and in Example 1, pages 29-32. Claims 116 and 118 recite that alkyl substituted acrylic acid groups include methacrylic acid groups, ethylacrylic acid groups, propylacrylic acid groups, and butylacrylic acid groups. Support for Claims 116 and 118 can be found in the specification as originally filed, for example, at page 10, line 31 through page 11, line 8.

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Conclusion

In view of the above amendments and foregoing remarks, applicants believe that Claims Claims 34-37, 57-69, 74-77, 101, and 102-118 are in condition for allowance. If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone applicants' attorney at (206) 695-1755.

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